REMARKS

The Applicants hereby elect to prosecute the claims of Group I, claims 1-24. The Applicants expressly reserve the right under 35 USC §121 to file a divisional application directed to the non-elected subject matter or any subject matter disclosed in this application during the pendency of this application. Applicants further reserve the right to petition for relief from the restriction requirement, particularly as applied to the "sub-invention" requirement.

In response to the "sub-invention" restriction requirement, Applicants elect with traverse the following species:

Rhomboid polypeptide - Human RHBDL-2

Characteristic to be modulated - Activity

Substrate - SEAP/6H/Spi/TGFα

Method - Cell culture

Applicants note that the Examiner has indicated a "SEQ ID NO:" next to the requirement for a specific Rhomboid polypeptide. The present application utilizes publicly known and available protein sequences in certain aspects of the invention. Among these known sequences is the elected species of rhomboid protein, human RHBDL2, which is disclosed in the specification in Table 1 (page 33), and which is further identified by Genbank accession number, and gene identification number. Applicants submit the intended sequence is clearly defined and does not require a sequence identifier.

Applicants elect the "sub-inventions" set forth above with traverse, and request rejoinder with respect to this invention.

Applicants note the recent guidance within USPTO with respect to restriction practice, and further note as stated by Director Burke, that under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j))." Further, "Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition."

The Examiner alleges that the individual sequences of the Rhomboid polypeptide and substrate polypeptide are distinct and represent separate "sub-inventions". However, the claimed invention relates to a new and non-obvious assay method for distinguishing proteolytic cleavage by rhomboid polypeptides from that of other types of protease.

A range of different rhomboid polypeptides could be used in the claimed assay methods. It is the assay method itself which is novel and non-obvious and the use of any specific rhomboid polypeptide in the claimed assay methods is not patentably distinct from the use of any other rhomboid polypeptide. Similarly, a range of different substrate polypeptides could be used in the claimed assay methods.

The use of any specific substrate polypeptide in the claimed assay methods is not patentably distinct from the use of any other rhomboid polypeptide in the claimed assay method. Patentability arises from the features of the assay method itself. Patentability does not arise from the choice of rhomboid polypeptide and substrate polypeptide, and a range of different rhomboid polypeptides and substrate polypeptides may be used in the claimed assay methods.

The assertion that individual rhomboid polypeptides and substrate polypeptide sequence represent separate "sub-inventions" is therefore unfounded.

Furthermore, the Examiner alleges that the sub-inventions of Group 1 do not relate to a single inventive concept under Rule 13.1 PCT because the only special technical feature which links the sub-inventions is "rhomboid proteases" and this is disclosed in Urban et al 2001.

Applicants submit this is incorrect. The present invention relates to assays which are able to distinguish proteolytic cleavage by rhomboid proteases from cleavage by other proteases. This is achieved by placing a tag upstream of a rhomboid cleavable transmembrane domain in a region which is not susceptible to cleavage by non-rhomboid proteases. Soluble proteolysis products containing the tag are therefore the products of rhomboid cleavage and not the products of non-rhomboid cleavage.

Assay methods which employ this arrangement of tag and rhomboid cleavable TMD are not disclosed in Urban et al. This arrangement, which is common to all the "sub-inventions" of Group I, therefore represents a special technical feature which confers unity of invention, across the entire subject-matter of Group I in accordance with Rule 13.1 PCT.

Reconsideration of the restriction requirement is therefore requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number MEWE-027.

Respectfully submitted,

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By: _____

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